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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,431	01/03/2007	Gerhard Tivig	2003P00775WOUS	9506

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER
BITAR, NANCY

ART UNIT	PAPER NUMBER
2624	

NOTIFICATION DATE	DELIVERY MODE
12/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,431	TIVIG ET AL.	
	Examiner	Art Unit	
	NANCY BITAR	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Appeal Brief filed 7/22/2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *3,4,12,14,16-18,20-22 and 24-28* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *3,4,12,14,16-18,20-22 and 24-28* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *19 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. In view of the appeal brief filed on 7/22/2011, PROSECUTION IS HEREBY REOPENED. A new ground of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 23 February 2010), Annex IV, reads as follows:

The USPTO recognizes that applicants may have claims directed to computer readable media that cover signals per se, which the USPTO must reject under 35 U.S.C. § 101 as covering both non-statutory subject matter and statutory subject matter. In an effort to assist the patent community in overcoming a rejection or potential rejection under 35 U.S.C. § 101 in this situation, the USPTO suggests the following approach. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments may be amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. § 101 by adding the limitation "non-transitory" to the claim. Cf. Animals - Patentability, 1077 Off. Gaz. Pat. Office 24 (April 21, 1987) (suggesting that applicants add the limitation "non-human" to a claim covering a multi-cellular organism to avoid a rejection under 35 U.S.C. § 101). Such an amendment would typically not raise the issue of new matter, even when the specification is silent because the broadest reasonable interpretation relies on the ordinary and customary meaning that includes signals per se. The limited situations in which such an amendment could raise issues of new matter occur, for example, when the specification does not support a non-transitory embodiment because a signal per se is the only viable embodiment such that the amended claim is impermissibly broadened beyond the supporting disclosure. See, e.g., Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473(Fed. Cir. 1998).

2. Claim 22 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 22 defines a "computer readable medium" embodying functional descriptive material. However, the claim does not define a non-transitory computer-readable medium or memory and is thus non-statutory for that reason (i.e., "examination the pending claims must be interpreted as broadly as their terms reasonably allow). The broadest reasonable interpretation of a claim drawn to a computer readable medium (also called machine readable medium and other such variations) typically covers forms of non-transitory tangible media and transitory propagating signals per se in view of the ordinary and

customary meaning of computer readable media, particularly when the specification is silent. See MPEP 2111.01. When the broadest reasonable interpretation of a claim covers a signal per se, the claim must be rejected under 35 U.S.C. § 101 as covering non-statutory subject matter. See In see Official Gazette Notice 1351 OG212, February 23,2010). That is, the scope of the presently claimed "computer readable medium " typically covers forms of non-transitory tangible media and transitory propagating signals *per se*. The examiner suggests amending the claim to add the limitation "non-transitory " to the claim or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

Examiner Notes

3. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 12, 14, 16-18, 20-22, 25,27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (2003/0101076) and further in view of Kawamura et al (US 4,931,864).

As to claim 20, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for a histogram including a updated in real time, (paragraph [0075], [0085]), during the conversion, generates a cumulative curve indication of the medical measurement data the cumulative curve being cumulative of the series of histogram values (figure 5, and 6) and displays the histogram with the cumulative curve superimposed, the histogram and the cumulative curve having common axes and a common scales (paragraph [0088-0089]). While Seely et a meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the variability display (paragraph [0085-0090] but fails to specifically teach the histogram includes an updates in real time values and generating a cumulative curve indicative of the medical measurement data the cumulative curve being cumulative of the series of histogram values. Specifically, Zaleski et al. teaches in FIG. 1, the system is implemented in computer hardware and software configured to operate on a dedicated software application and Web-enabled hardware computing system to access raw medical facts about patients extracted from lifetime clinical records and telemetry from available modalities (such as ventilators, pulse oximeters,

ECG monitors, core temperature probes, etc.); and to convert this raw data into mathematical models for clinical outcome and real-time patient state prediction. Zelski et al. teaches the model (expected) trajectories are compared with the measured (actual) trajectories of the patient. The comparison is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual trajectories. Finally, by combining all trajectories together, it is possible to determine a cumulative estimate of "sameness" using a .chi..sup.2-square test to show that the patient's cardiovascular parameters are either following or not following an expected path (see paragraph [0058-0060]) . It would have been obvious to one of ordinary skill in the art to generate in real-time the histogram data and the cumulative curve in Seely display in order to have an efficient system which is capable of acting as the foundation on which to establish predictive methodologies for clinical application that would provide significant advantages in the process of defining a truly valuable decision support system for the clinician thus providing a convenient way to perform complex comparative trend analysis . Seely discloses displaying a histogram of medical measurements shown in Figs 6A and B. Zaleski discloses displaying a cumulative curve but none of them is disclosing displaying both superimposed on each other. Specifically, Kawamura al teaches cumulative intensity distribution curve is commonly used for the signals R, G and B to obtain an output image with a sufficient tonal rendition over the entire area, but it is also possible to adopt different cumulative distribution curves for the different colors (column 3, lines 27-32). Kawamura et al teaches a curve a in FIG. 2 is a histogram of the intensity distribution represented by said equation over the entire frame to be recorded, for example over 640.times.480 dots in NTSC signal. Also a curve b in FIG. 2 shows a cumulative intensity distribution obtained from said histogram (column 3, lines 1-32). It would

have been obvious to one skilled in the art to superimpose the cumulative curve on a histogram as taught by Kawamura with the medical data of Seely in order to have a clear and simple long term analysis .Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically an attending physician, may select the number of data points m.sub.k to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 20, wherein, during the conversion, the computer generates aids for the retrospective analysis of the histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]; see also Kawamura et al figure 2 and 3).

The limitation of claim 12 has been addressed in claim 20 above.

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal

or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 28, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]; see also Zaleski et al paragraph [0039-0040]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5; note that Zaleski teaches The ongoing results of the analysis (e.g. the trend) may then be transmitted by Application Server 104 back to User

Interface 105, such as in the form of a graphical display that is updated in real time; see paragraph [0050]).

As to claim 21, Seely teaches the retrospective analysis aids include at least one of: a cumulative curve cursor for determining a percentage of time that histogram values are below a current cumulative cursor position; range-selection cursors for determining a percentage of time that histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data; and a deviation and direction-change readout that shows deviation from a mean histogram value and a direction of measurement data change (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

The limitation of claims 22, 27 and 28 has been addressed above.

As to claim 25, Seely teaches the medical monitoring device as claimed in claim 28, wherein the histogram data includes a series of medical measurement values and the cumulative curve includes a sum of the medical measurement values (paragraph [0085]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 12, 14, 16-18, 20-22, 25,27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (2003/0101076) and further in view of John et al (US 4,974,598).

As to claim 20, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for a histogram including a updated in real time, (paragraph [0075], [0085]), during the conversion, generates a cumulative curve indication of the medical measurement data the cumulative curve being cumulative of the series of histogram values (figure 5, and 6) and displays the histogram with the cumulative curve superimposed, the histogram and the cumulative curve having common axes and a common scales (paragraph [0088-0089]). While Seely et a meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the

variability display (paragraph [0085-0090] but fails to specifically teach the histogram includes an updates in real time values and generating a cumulative curve indicative of the medical measurement data the cumulative curve being cumulative of the series of histogram values. Specifically, Zaleski et al. teaches in FIG. 1, the system is implemented in computer hardware and software configured to operate on a dedicated software application and Web-enabled hardware computing system to access raw medical facts about patients extracted from lifetime clinical records and telemetry from available modalities (such as ventilators, pulse oximeters, ECG monitors, core temperature probes, etc.); and to convert this raw data into mathematical models for clinical outcome and real-time patient state prediction. Zelski clearly teaches the model (expected) trajectories are compared with the measured (actual) trajectories of the patient. The comparison is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual trajectories. Finally, by combining all trajectories together, it is possible to determine a cumulative estimate of "sameness" using a .chi..sup.2-square test to show that the patient's cardiovascular parameters are either following or not following an expected path (see paragraph [0058-0060]) . It would have been obvious to one of ordinary skill in the art to generate in real-time the histogram data and the cumulative curve in Seely display in order to have an efficient system which is capable of acting as the foundation on which to establish predictive methodologies for clinical application that would provide significant advantages in the process of defining a truly valuable decision support system for the clinician thus providing a convenient way to perform complex comparative trend analysis . Seely discloses displaying a histogram of medical measurements shown in Figs 6A and B. Zaleski discloses displaying a cumulative curve but none of them is disclosing displaying both superimposed on each other.

Specifically, John al figure 4 that teaches in item 62 the histogram displays wherein the curve is superimposed on the phase histogram (see column 11, lines 26-48).It would have been obvious to one skilled in the art to superimpose the cumulative curve on a histogram in order to have a clear and simple format displayed analysis of the result thus minimizing ambiguous conclusions (column 3, lines 3-15).Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically an attending physician, may select the number of data points m.sub.k to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 20, wherein, during the conversion, the computer generates aids for the retrospective analysis of the histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]; see also John et al figure 4, item 62).

The limitation of claim 12 has been addressed in claim 20 above.

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set.

This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 28, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]; see also Zaleski et al paragraph [0039-0040]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising display means for displaying real-time signal patterns of the medical

measurement data (real-time display, 502, figure 5; note that Zaleski teaches The ongoing results of the analysis (e.g. the trend) may then be transmitted by Application Server 104 back to User Interface 105, such as in the form of a graphical display that is updated in real time; see paragraph [0050]).

As to claim 21, Seely teaches the retrospective analysis aids include at least one of: a cumulative curve cursor for determining a percentage of time that histogram values are below a current cumulative cursor position; range-selection cursors for determining a percentage of time that histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data; and a deviation and direction-change readout that shows deviation from a mean histogram value and a direction of measurement data change (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

The limitation of claims 22, 27and 28 has been addressed above.

As to claim 25, Seely teaches the medical monitoring device as claimed in claim 28, wherein the histogram data includes a series of medical measurement values and the cumulative curve includes a sum of the medical measurement values (paragraph [0085]).

Allowable Subject Matter

1. Claims 24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy Bitar/
Examiner, Art Unit 2624

/Matthew C Bella/
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